

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-20 (Canceled)

21. (Previously Presented) A semi-solid or solid pharmaceutical composition comprising a basic drug compound, Vitamin E TPGS, and a physiologically tolerable water-soluble acid wherein the acid:drug compound ratio is ranges from 1:1 to 100:1 by weight.

22. (Previously Presented) The composition according to claim 21 wherein the basic drug compound, Vitamin E TPGS and the acid are intimately admixed.

23. (Previously Presented) The composition according to claim 21 wherein the physical state of said composition is a solid dispersion.

24. (Previously Presented) The composition according to claim 21 wherein the acid is citric, fumaric, tartaric, maleic, malic, succinic, oxalic, malonic, benzoic, mandelic, or ascorbic acid.

25. (Previously Presented) The composition according to claim 24 wherein the acid is citric acid.

26. (Previously Presented) The composition according to claim 21 further comprising an organic polymer.

27. (Previously Presented) The composition according to claim 26 wherein the polymer is selected from alkylcelluloses, hydroxyalkylcelluloses, hydroxyalkyl alkylcelluloses, carboxyalkylcelluloses, alkali metal salts of carboxyalkylcelluloses, carboxyalkylcellulose esters, starches, pectins, chitosan, heparin, heparinoids, polysaccharides, polyacrylic acids and salts

thereof, polymethacrylic acids and salts thereof, methacrylate copolymers, polyvinylalcohol, polyvinylpyrrolidone, copolymers of polyvinylpyrrolidone with vinyl acetate, polyalkylene oxides, and copolymers of ethylene oxide and propylene oxide.

28. (Previously Presented) The composition according to claim 27 wherein the polymer is selected from methylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxybutylcellulose, hydroxyethyl methylcellulose, hydroxypropyl methylcellulose, carboxymethylcellulose, sodium carboxymethylcellulose, carboxymethylethylcellulose, sodium carboxymethylamylopectin, chitosan, alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, tragacanth, agar-agar, gum arabic, guar gum, xanthan gum, polyethylene oxide, polypropylene oxide, poloxamers, and poloxamines.

29. (Previously Presented) The composition according to claim 26 wherein the polymer has an apparent viscosity of 1 - 100 mPa.s when dissolved in a 2% aqueous solution at 20 °C.

30. (Previously Presented) The composition according to claim 26 wherein the polymer is hydroxypropylmethylcellulose.

31. (Previously Presented) The composition according to claim 26 wherein the polymer is a water soluble polymer having an apparent viscosity of more than 1,000 mPa.s when dissolved in a 2% aqueous solution at 20 °C and wherein the composition provides sustained release of the drug.

32. (Previously Presented) The composition according to claim 1 wherein the basic drug compound is no more than sparingly soluble in water.

33. (Previously Presented) The composition according to claim 1 wherein the drug compound is

4-[[4-[[4-(2-cyanoethyl)-2,6-dimethylphenyl]amino]-2-pyrimidinyl]amino]-benzonitrile;
4-[[2-[(cyanophenyl)amino]-4-pyrimidinyl]amino]-3,5-dimethylbenzonitrile;
4-[[4-[(2,4,6-trimethylphenyl)amino]-2-pyrimidinyl]amino]benzonitrile;
4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenoxy)-2-pyrimidinyl]-amino]-benzonitrile;
or a pharmaceutically acceptable salt or stereochemically isomeric form thereof.

34. (Previously Presented) The composition according to claim 1 wherein Vitamin E TPGS is present in a concentration of 1 to 70 % by weight relative to the total weight of Vitamin E TPGS, acid, and basic drug compound.

35. (Previously Presented) The composition according to claim 1 wherein Vitamin E TPGS is present in a concentration of 5 to 55 % by weight relative to the total weight of Vitamin E TPGS, acid, and basic drug compound.

36. (Previously Presented) The composition according to claim 1 wherein Vitamin E TPGS is present in a concentration of 10 to 50 % by weight relative to the total weight of Vitamin E TPGS, acid, and basic drug compound.

37. (Previously Presented) The composition according to claim 1 wherein the weight by weight ratio of Vitamin E TPGS to basic drug compound is in the range of from 100:1 to 1:5.

38. (Previously Presented) The composition according to claim 1 wherein the weight by weight ratio of Vitamin E TPGS to basic drug compound is in the range of from 50:1 to 1:2.

39. (Previously Presented) The composition according to claim 1 wherein the weight by weight ratio of Vitamin E TPGS to basic drug compound is in the range of from 10:1 to 1:1.

40. (Previously Presented) A pharmaceutical dosage form comprising a therapeutically effective amount of a pharmaceutical composition as defined in claim 1.

41. (Previously Presented) The dosage form of claim 40 wherein the dosage form is adapted for topical administration or administration into the nose, lungs, mouth, ear, stomach, rectum, or vagina.

42. (Previously Presented) The dosage form of claim 40 wherein said composition is filled into a standard capsule, or is mixed with at least one bulking agent and compressed into a tablet.

43. (Withdrawn) A method of treating a mammal with an oral pharmaceutical composition, comprising administering the pharmaceutical composition as a pharmaceutical composition according to claim 1 at any time of the day independent of any food taken in by said mammal.

44. (Withdrawn) A pharmaceutical package suitable for commercial sale comprising a container, an oral dosage form as claimed in claim 1, and associated with said package, written matter non-limited as to whether the dosage form can be administered with or without food.

45. (Withdrawn) A process for preparing a composition according to claim 1 comprising: dissolving a basic drug compound, Vitamin E TPGS, a physiologically tolerable water-soluble acid, and optionally a physiologically tolerable water-soluble organic polymer, in a solvent; removing the solvent from the resultant solution to form the resultant product; optionally forming the resultant product into desired shapes; and optionally coating the resulting product with a physiologically tolerable coating material.

46. (Withdrawn) The process according to claim 45 wherein the solvent is removed by spray-drying.

47. (Withdrawn) The process according to claim 45 wherein the solvent is removed by freeze-drying.

48. (Withdrawn) The process according to claim 45 wherein the solvent is a supercritical fluid.

49. (Withdrawn) A process according to claim 48 wherein the supercritical fluid is removed by decompression.

50. (Withdrawn) The process according to claim 48 wherein the supercritical fluid technology is Rapid Expansion of Supercritical Solutions or particles from Gas Saturated Solutions.

51. (Withdrawn) The process according to claim 45 further comprising adding a supercritical fluid, in addition to the solvent.

52. (Withdrawn) The process according to claim 51 wherein the supercritical fluid technology is Gas Anti Solvent, Solution Enhanced Dispersion by Supercritical fluids, Aerosol Solvent Extraction System, Supercritical Anti Solvent, or Precipitation with Compressed Antisolvent.

53. (Withdrawn) The process according to claim 45 wherein the solution is coated, sprayed or granulated onto a suitable carrier followed by evaporating the solvent.

54. (Withdrawn) The process according to claim 53 wherein the solution is granulated onto a suitable carrier followed by evaporating the solvent.

55. (Withdrawn) The process according to claim 53 wherein the solvent is evaporated by drying at elevated temperatures and/or under vacuum or by applying microwaves.

56. (Withdrawn) The process according to claim 53 wherein the carrier is microcrystalline cellulose, fumed SiO₂, or an inert core.

57. (Withdrawn) The process according to claim 56 wherein the carrier is fumed SiO₂.

58. (Withdrawn) The process according to claim 53 wherein the process is carried out in a high shear granulator.

59. (Withdrawn) The process according to claim 45 wherein the process is performed in an extruder.

60. (Withdrawn) The process according to claim 59 wherein the solution of the components of the composition is granulated onto a suitable carrier and the resultant wetted powder is extruded.

61. (Withdrawn) A process of preparing a composition according to claim 1 comprising: co-melting a basic drug compound, Vitamin E TPGS, a physiologically tolerable water-soluble acid and optionally a physiologically tolerable water-soluble organic polymer; and optionally forming the resultant product into desired shapes; and optionally coating the resulting product with a physiologically tolerable coating material.

62. (Withdrawn) The process according to claim 61 wherein the co-melting is performed by meltextrusion.

63. (Withdrawn) The process according to claim 61 wherein the resultant product is granulated, sprayed or coated onto a suitable carrier.

64. (Withdrawn) The process according to claim 61 wherein the resultant product is granulated onto a suitable carrier.

65. (Withdrawn) The process according to claim 64 wherein the carrier is microcristalline cellulose, fumed SiO_2 , or an inert core.

66. (Withdrawn) The process according to claim 64 wherein the carrier is fumed SiO_2 .

67. (Withdrawn) The process according to claim 61 wherein the process is carried out in a high shear granulator.